



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2022-0008]

RIN 0651-AD60

Standardization of the Patent Term Adjustment Statement Regarding Information Disclosure Statements

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) proposes to revise the rules of practice pertaining to patent term adjustment to require that the patent term adjustment statement regarding information disclosure statements be submitted on an Office form. Use of the Office form will streamline certain aspects of prosecution by more accurately capturing and accounting for the patent term adjustment without unnecessary back-and-forth between the USPTO and applicant. It will also save resources by eliminating the need for a manual review of the patent term adjustment statement.

DATES: Comments must be received by **[INSERT DATE 60 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to ensure consideration.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO-P-2022-0008 on the homepage and click

“Search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this document and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in Adobe® portable document format or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below (at **FOR FURTHER INFORMATION CONTACT**) for special instructions.

FOR FURTHER INFORMATION CONTACT: Kery Fries, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7757. You can also send inquiries by email to patentpractice@uspto.gov.

SUPPLEMENTARY INFORMATION: This rulemaking pertains to the patent term adjustment regulations establishing the circumstances that will, or will not, be considered a failure of an applicant to engage in reasonable efforts to conclude prosecution (processing or examination) of an application and any resulting reduction of patent term adjustment (37 CFR 1.704).

Regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application and the resulting reduction of any patent term adjustment are set forth in 37 CFR 1.704(c)(1) through (14).

Additionally, 37 CFR 1.704(d)(1) provides a safe harbor by setting forth the circumstances that will not be considered a failure to engage in reasonable efforts to conclude processing or examination of the application. Specifically, 37 CFR 1.704(d)(1) provides that a paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under 37 CFR 1.704(c)(6), (8), (9), or (10) if it is accompanied by the required statement. The provision at 37 CFR 1.704(d)(1) also provides that a request for continued examination in compliance with § 1.114 with no submission other than an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under 37 CFR 1.704(c)(12) if it is accompanied by the required statement. The statement required to accompany the paper or request for continued examination must state that each item of information contained in the information disclosure statement (1) was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or (2) is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

This rulemaking proposes amending 37 CFR 1.704(d) to include new paragraph (d)(3) requiring that filers submit the patent term adjustment statement under 37 CFR 1.704(d)(1) on the Office form (PTO/SB/133) to derive benefit under 37 CFR 1.704(d). The changes proposed in this rulemaking facilitate the current patent term adjustment statement requirement through the use of an existing Office form.

Form PTO/SB/133 includes the patent term adjustment statement required by 37 CFR 1.704(d)(1). Specifically, the form includes the statement that “[e]ach item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.” The form also includes the alternative statement that “[e]ach item of information contained in the information disclosure statement is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.” The filer of the form could select one or both of these statements.

Use of form PTO/SB/133 aims to: (1) ensure the accurate capture of the presence of a patent term adjustment statement under 37 CFR 1.704(d)(1) by the USPTO’s IT system, and (2) eliminate the need to manually review an applicant’s patent term adjustment statement to determine whether it is proper under 37 CFR 1.704(d)(1). Furthermore, as a result of using the form, the USPTO’s automated process for calculating patent term adjustment will be more likely to account for the patent term adjustment statement, thereby eliminating the need to file a request for reconsideration of patent term adjustment under 37 CFR 1.705(b). Form PTO/SB/133 is available at www.uspto.gov/sites/default/files/documents/sb0133.pdf. The Office of Management and Budget (OMB) has determined that, under 5 CFR 1320.3(h), form PTO/SB/133 does not collect “information” within the meaning of the Paperwork Reduction Act of 1995.

Filers who submit a 37 CFR 1.704(d)(1) patent term adjustment statement without using Office form PTO/SB/133 and filers who submit Office form PTO/SB/133 with any modification to the patent term adjustment statement (that is, modifications to either or

both of the statements indicated on the form) will not receive the benefit of the safe harbor under 37 CFR 1.704(d). Under such circumstances, the concurrently filed paper containing only an information disclosure statement, in compliance with §§ 1.97 and 1.98, or the concurrently filed paper containing a request for continued examination, in compliance with § 1.114, with no submission other than an information disclosure statement, in compliance with §§ 1.97 and 1.98, will be treated as not accompanied by a patent term adjustment statement under 37 CFR 1.704(d)(1).

Additionally, the USPTO's patent term adjustment algorithm is being modified to detect when a patent term adjustment statement under 37 CFR 1.704(d)(1) is filed using the Office form. The Office has created a particular document code for the filing of this patent term adjustment statement form under 37 CFR 1.704(d). Once modified, the patent term adjustment algorithm will recognize that the Office form (PTO/SB/133) has been filed concurrently with (i.e., on the same date as) the information disclosure statement and, accordingly, will not assess a reduction in patent term adjustment under the applicable applicant delay sections of 37 CFR 1.704(c) for the patent.

The Office reviewed a sampling of patent term adjustment statements that were independently submitted without the use of Office form PTO/SB/133 and found that a portion of those statements were deficient by failing to meet the required language of 37 CFR 1.704(d). Requiring the use of the form will eliminate these types of deficiencies, and use of Office form PTO/SB/133 will thus ensure legal compliance, so long as the patent term adjustment statement is not modified. Because the USPTO's patent term adjustment algorithm will now automatically determine that a reduction in patent term should not be assessed in view of a submitted form PTO/SB/133, the Office will also not need to expend resources to manually review the provided patent term adjustment statement under 37 CFR 1.704(d). The Office will rely on the presentation to the Office (whether by signing, filing, submitting, or later advocating) of this form, whether by a

practitioner or non-practitioner, as a certification under 37 CFR 11.18(b) that the existing text and any certification statements on the form have not been altered.

The submission of a patent term adjustment statement under 37 CFR 1.704(d) does not require a fee. However, in certain cases, a fee is required. Specifically, the Office has provided a procedure for applicants to seek a waiver under 37 CFR 1.183 to allow for a late-filed patent term adjustment statement under 37 CFR 1.704(d). Section 1.183 provides for an applicant to petition for suspension of rules and requires the fee under 37 CFR 1.17(f). If accompanied by a petition under 37 CFR 1.183, an applicant may submit the patent term adjustment statement under 37 CFR 1.704(d) after the timely filing of the information disclosure statement. Applicants have additionally submitted such a patent term adjustment statement under 37 CFR 1.704(d) accompanied by a petition under 37 CFR 1.183 along with the filing of a request for reconsideration of the patent term adjustment indicated on the patent (37 CFR 1.705(b)) in order to receive the benefit of the safe harbor under 37 CFR 1.704(d). The Office has generally granted such 37 CFR 1.183 petitions.

Once the USPTO's patent term adjustment algorithm is modified to automatically detect when a patent term adjustment statement form under 37 CFR 1.704(d) is filed, the Office may consider eliminating the procedure of generally granting such 37 CFR 1.183 petitions. Additionally, applicants should keep in mind that a petition under 37 CFR 1.183 may only be used to request acceptance of the late-filed patent term adjustment statement under 37 CFR 1.704(d)(1). Under no circumstances may the information disclosure statement be filed more than 30 days from the applicable communication under 37 CFR 1.704(d)(1)(i) or (ii), the 30-day period being non-extendable per 37 CFR 1.704(d)(2).

Discussion of Specific Rules:

The following is a discussion of the proposed amendments to 37 CFR part 1.

Section 1.704: Section 1.704(d) is proposed to be amended to include new paragraph (d)(3) requiring that the statement under paragraph (d)(1) of this section be submitted on a form provided by the Office (PTO/SB/133). Absent the patent term adjustment statement under 37 CFR 1.704(d) provided on the Office form, submitted concurrently with the information disclosure statement, an applicant will be assessed a reduction of the period of patent term adjustment under the appropriate provision in § 1.704. Newly proposed § 1.704(d)(3) also includes language, mirroring that in existing § 1.4(d)(5), regarding the prohibition of changing an existing form's text and patent term adjustment statements.

Rulemaking Considerations

A. Administrative Procedure Act: The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.” (citation and internal quotation marks omitted)); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *Bachow Commc’ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.). Specifically, this rulemaking proposes to revise Office rules to require the use of the provided Office form for filing statements under 37 CFR 1.704(d).

The proposed revision creates paragraph 37 CFR 1.704(d)(3) requiring that the “statement under paragraph (d)(1) of this section must be submitted on the Office form (PTO/SB/133) provided for such a patent term adjustment statement.”

Accordingly, prior notice and opportunity for public comment for the changes proposed by this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. See *Perez*, 135 S. Ct. at 1206 (Notice-and-comment procedures are required neither when an agency “issue[s] an initial interpretive rule” nor “when it amends or repeals that interpretive rule.”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and-comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(A))). However, the Office has chosen to seek public comment before implementing the rule to benefit from the public’s input.

B. Regulatory Flexibility Act: For the reasons set forth herein, the Senior Counsel for Regulatory and Legislative Affairs, Office of General Law, of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes in this proposed rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This rulemaking does not propose to impose any additional fees on applicants. This rulemaking specifically proposes to revise Office rules to require the use of an Office form for statements under 37 CFR 1.704(d)(1) through the creation of paragraph 37 CFR 1.704(d)(3). This new requirement only seeks to facilitate the current statement requirement, pursuant to 37 CFR 1.704(d)(1) and set forth in the Manual of Patent Examining Procedure 2732, through the use of an existing Office form containing the required statement language.

For the foregoing reasons, the changes in this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the proposed rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a

tribal summary impact statement is not required under Executive Order 13175

(Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211

(May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801-808), the USPTO will submit a report containing any final rule resulting from this rulemaking and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of \$100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based

enterprises to compete with foreign-based enterprises in domestic and export markets.

Therefore, this rulemaking is not a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of \$100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of \$100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 et seq.

M. National Environmental Policy Act of 1969: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. The rules of practice pertaining to patent term adjustment and extension have been reviewed and approved by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0020. Although this action proposes a requirement to use Office form PTO/SB/133 when making a statement under 37 CFR 1.704(d), OMB has determined that, under 5 CFR 1320.3(h), form PTO/SB/133 does not collect

“information” within the meaning of the Paperwork Reduction Act of 1995. Because the changes proposed in this rulemaking would not affect the information collection requirements or fees associated with the information collections approved under OMB control number 0651-0020 or any other information collection, the Office is not resubmitting an information collection package to OMB for its review and approval.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

P. E-Government Act Compliance: The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and record keeping requirements, Small businesses.

For the reasons set forth in the preamble, USPTO proposes to amend 37 CFR part 1 as follows:

PART 1 - RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Section 1.704 is amended by adding new paragraph (d)(3) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

(d) * * *

(3) The statement under paragraph (d)(1) of this section must be submitted on the Office form (PTO/SB/133) provided for such a patent term adjustment statement. Otherwise, the paper or request for continued examination will be treated as not accompanied by a statement under paragraph (d)(1) of this section. No changes to statements on this Office form may be made. The presentation to the Office (whether by signing, filing, submitting, or later advocating) of this form, whether by a practitioner or non-practitioner, constitutes a certification under § 11.18(b) of this chapter that the existing text and any certification statements on this form have not been altered.

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Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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